Perioperative validation of the non-invasive hemodynamic measuring device TL-400

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26680

Source
NTR

Health condition

hemodynamic changes, low blood pressure, fluid challenge, vasopressant/inotropic agent administration, measurement cardiac output, measurement blood pressure, non invasive cardiac output measurement. hemodynamische veranderingen , vocht bolus, cardiac output meting, bloeddruk meting, non invasieve cardiac output meting

Sponsors and support

Primary sponsor: Radboud university medical centre
Source(s) of monetary or material Support: Radboud university medical centre

Intervention

Outcome measures

Primary outcome

Cardiac output, systolic blood pressure, diastolic blood pressure, mean blood pressure, stroke volume

Secondary outcome

none

Study description

Background summary

Perioperative validation study to compare TL-400 hemodynamic device with the standard PiCCO measuring device by comparing simultaneous CO and BP measurements at predetermined time points

Study objective

Are hemodynamic values obtained by the non invasive hemodynamic measuring device TL-400 comparable with the values obtained by the standard invasive hemodynamic measuring devices (transpulmonary thermodilution (TPTD) (PiCCO system; Pulsion Medical Systems) or pulmonary artery catheter (PAC)

Study design

Simultaneous CO and BP measurements were performed at seven predetermined time points (T1-T7): after induction of general anaesthesia but before surgical incision (T1), 30 minutes after start CRS (T2), 30 minutes before end of CRS or halfway iv chemotherapy (T3), after CRS and before the start HIPEC procedure (T4), halfway through HIPEC (T5), after the end of chemotherapy perfusion (T6), end of surgery (T7)

Intervention

After insertion of the standard invasive measuring device, the TL 400 sensor is placed around the wrist at the point where the radial artery is palpable over the head of the os radius.

Contacts

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Eligibility criteria

Inclusion criteria

All patients receiving invasive hemodynamic monitoring as standard perioperative monitoring are eligible for inclusion.

Age > 18 years

Exclusion criteria

Severe peripheral vascular disease

Severe tricuspid or aortic valve regurgitation

Anatomical abnormalities at the wrist so the TL-400 brace cannot be applied.

Refusal of the patient

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-12-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6812

Register	ID
NTR-old	NTR6998
Other	METC RadboudUMC : 2017-3203

Study results